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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: John Ghrayeb, David M. Knight and James E. Looney
Application No.: 09/896,050 Group Art Unit: 1644
Filed: June 29, 2001 Examiner: Ronald B. Schwadron, Ph.D.
Confirmation No.: 1490
Title: CHIMERIC IMMUNOGLOBULIN FOR CD4 RECEPTORS

CERTIFICATE OF MAILING OR TRANSMISSION	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, or is being facsimile transmitted to the United States Patent and Trademark Office on:	
December 3, 2003	<i>Shannon Luis</i>
Date	Signature
<i>Shannon Luis</i>	
Typed or printed name of person signing certificate	

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

- ☐ under 37 CFR 1.129(a), or
(First/Second submission after Final Rejection)
- ☐ under 37 CFR 1.97(b), or
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).
- ☒ under 37 CFR 1.97(c) together with either:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, or
- ☒ a \$180.00 fee under 37 CFR 1.17(p), or
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
- ☐ under 37 CFR 1.97(d) together with:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, and
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)
- ☐ under 37 CFR 1.97(i):
Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.
(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
- ☒ Copies of the cited references (AB, AL2-AQ2, AL3, AX5-AZ5, AR6-AZ6, AR7-AZ7, AR8-AZ8 and AR9) are enclosed.
- ☐ Since this application was filed after June 30, 2003, copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
- ☐ Copies of the cited references are enclosed except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]
- ☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
- ☐ The "concise explanation" requirement (non-English references) for reference(s) [] under 37 CFR 1.98(a)(3) is satisfied by:
- ☐ the explanation provided on the attached sheet.
- ☐ the explanation provided in the Specification.
- ☐ submission of the enclosed International Search Report.
- ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
- ☐ the enclosed English language abstract.

☐ Applicant requests that the following non-published pending applications be considered:

Examiner's
Initials

_____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []
 _____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []
 _____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

Examiner

Date

- ☐ A copy of each above-cited application, including the current claims, is enclosed.
- ☐ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

REMARKS

This Supplemental Information Disclosure Statement is being filed to make references that were cited in an opposition proceedings in a related European Patent (EP 0 511 308) of record. Some of the references cited in the opposition proceedings are already of record in this application and are not being resubmitted.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

- [X] A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- [] Please charge Deposit Account 08-0380 in the amount of \$[]. A copy of this Statement is enclosed.
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Respectfully submitted,

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Dated: *December 3, 2003*

PTO-1449 REPRODUCED		ATTORNEY DOCKET NO. 0148.1102-011	APPLICATION NO. 09/896,050	
SUPPLEMENTAL INFORMATION DISCLOSURE CITATION IN AN APPLICATION December 3, 2003 (Use several sheets if necessary)		APPLICANT John Ghrayeb <i>et al.</i>		
		FILING DATE June 29, 2001	CONFIRMATION NO. 1490	GROUP 1644

U.S. PATENT DOCUMENTS				
EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER	ISSUE DATE / PUBLICATION DATE	NAME
	AB	4,381,295	26-APR-1983	Kung <i>et al.</i>

FOREIGN PATENT DOCUMENTS					
		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION YES NO
	AL2 ✓	EP 0 125 023 A1 ✓	14-NOV-1984	EPO	
	AM2 ✓	EP 0 240 344 B1	07-OCT-1987	EPO	
	AN2 ✓	EP 0 200 412 A2	10-DEC-1986	EPO	
	AO2 ✓	EP 0 171 496 A2	19-FEB-1986	EPO	
	AP2 ✓	EP 0 173 494 A2	05-MAR-1986	EPO	
	AQ2 ✓	WO 86/01533 A1	13-MAR-1986	PCT	
	AL3 ✓	EP 0 511 308 B1	04-NOV-1992	EPO	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)	
AX5 ✓	Kong, Y. M., <i>et al.</i> , "Pathogenic Mechanisms in Murine Autoimmune Thyroiditis: Short- and Long-Term Effects of <i>in vivo</i> depletion of CD4 ⁺ and CD8 ⁺ Cells," <i>Clin. Exp. Immunol.</i> , 77:428- 433 (1989).
AY5 ✓	Cobbold, S.P., <i>et al.</i> , "Therapy with Monoclonal Antibodies by Elimination of T-Cell Subsets <i>in vivo</i> ," <i>Nature</i> , 312:548-551 (1984).
AZ5 ✓	Mudgett-Hunter, M., <i>et al.</i> , "Binding and Structural Diversity Among High-Affinity Monoclonal Anti-Digoxin Antibodies," <i>Molecular Immunology</i> , 22(4):477-488 (1985).
AR6 ✓	Playfair, J.H.L., "Antigen-Antibody Interaction and Immune Complexes," In <i>Immunology At a Glance</i> , (Blackwell Scientific Publication; London), Chapter 14 (1984).
AS6 ✓	Evans, R.L., <i>et al.</i> , "Thymus-Dependent Membrane Antigens in Man: Inhibition of Cell-Mediated Lympholysis by Monoclonal Antibodies to T _{H2} Antigen," <i>Proc. Natl. Acad. Sci.</i> , 78(1):544-548 (1981).
AT6 ✓	Matthews, T.J., <i>et al.</i> , "AIDS Vaccines", <i>Scientific American</i> , 259(4):98-105 (1988).

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

✓	AU6	van Oosten, B.W., <i>et al.</i> , "Treatment of Multiple Sclerosis with the Monoclonal Anti-CD4 Antibody cM-T412: Results of a Randomized, Double-Blind, Placebo-Controlled, MR-Monitored Phase II Trial," <i>Neurology</i> , 49:351-357 (1997).
✓	AV6	Moreland, L.W., <i>et al.</i> , "Experience with a Chimeric Monoclonal Anti-CD4 Antibody in the Treatment of Refractory Rheumatoid Arthritis," <i>Clinical and Experimental Rheumatology</i> , 11(Suppl. 8):S153-S159 (1993)
✓	AW6	Gill, H.S., <i>et al.</i> , "In vivo Inhibition by a Monoclonal Antibody to CD4 ⁺ T Cells of Humoral and Cellular Immunity in Sheep," <i>Immunology</i> , 77:38-42 (1992).
✓	AX6	Bushell, A., <i>et al.</i> , "Transplantation Tolerance Induced by Antigen Pretreatment and Depleting Anti-CD4 Antibody Depends on CD4 ⁺ T Cell Regulation During the Induction Phase of the Response," <i>Eur. J. Immunol.</i> , 25:2643-2649 (1995).
✓	AY6	Matloubian, M., <i>et al.</i> , "CD4 ⁺ Cells are Required to Sustain CD8 ⁺ Cytotoxic T-Cell Responses During Chronic Viral Infection," <i>Journal of Virology</i> , 68(12):8056-8063 (1994).
✓	AZ6	Canva-Delcambre, V., <i>et al.</i> , "Treatment of Severe Crohn's Disease with Anti-CD4 Monoclonal Antibody," <i>Ailment Pharmacol. Ther.</i> , 10:721-727 (1996).
✓	AR7	van Montfrans, C., <i>et al.</i> , "Immunotherapy of Crohn's Disease," <i>Mediators of Inflammation</i> , 7:149-152 (1998).
✓	AS7	Reiter, C., <i>et al.</i> , "Treatment of Rheumatoid Arthritis with Monoclonal CD4 Antibody M-T151. Clinical Results and Immunopharmacologic Effects in an Open Study, Including Repeated Administration," <i>Arthritis and Rheumatism</i> , 34(5):525-536 (1991).
✓	AT7	Moreland, L.W., <i>et al.</i> , "Use of a Chimeric Monoclonal Anti-CD4 Antibody in Patients with Refractory Rheumatoid Arthritis," <i>Arthritis and Rheumatism</i> , 36(3):307-318 (1993).
✓	AU7	Boehringer Mannheim Biochemicals Catalogue, page 328, 1987/1988.
✓	AV7	Boehringer Mannheim Biochemicals Catalogue, page 109, 1989.
✓	AW7	Genbank Accession No. PH1224, "Ig Kappa Chain Precursor V Region (M-T151) - Mouse (fragment)," (1999) [online], [retrieved on 4/10/00]. Retrieved from www.ncbi.nlm.nih.gov :80.

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	APPLICANT John Ghrayeb <i>et al.</i>		
	FILING DATE June 29, 2001	CONFIRMATION NO. 1490	GROUP 1644

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AX7	Genbank Accession No. PH1225, "Ig Heavy Chain Precursor V Region (M-T151) - Mouse (fragment)," (1999) [online], [retrieved on 4/10/2000]. Retrieved from www.ncbi.nlm.nih.gov:80.
AY7	Genbank Accession No. S19970, "Ig Kappa Chain V Region (M-T151) - Mouse (fragment)," (1999) [online], [retrieved on 4/10/2000]. Retrieved from www.ncbi.nlm.nih.gov:80.
AZ7	Genbank Accession No. S19963, "Ig Heavy Chain V Region (M-T151) - Mouse (fragment)," (1996) [online], [retrieved on 4/10/2000]. Retrieved from www.ncbi.nlm.nih.gov:80.
AR8	Genbank Accession No. CAA46223, "Alpha CD4 mAb Immunoglobulin Light Chain VJ Region [Mus musculus]," (1997) [online], [retrieved on 4/10/00]. Retrieved from www.ncbi.nlm.nih.gov:80.
AS8	Genbank Accession No. CAA46215, "Alpha CD4 mAb Immunoglobulin Heavy Chain VDJ Region [Mus Musculus]," (1997) [online], [retrieved on 4/10/00]. Retrieved from www.ncbi.nlm.nih.gov:80.
AT8	Genbank Accession No. AAB24319, "Anti-CD4 mAb M-T151 Variable Region Heavy Chain {J4, Chimeric Antibody} [Mice, Hybridoma Cells, Peptide Partial, 139 aa]," (1993) [online], [retrieved on 4/10/00]. Retrieved from www.ncbi.nlm.nih.gov:80.
AU8	Genbank Accession No. AAB24318, "Anti-CD4 mAb M-T151 Variable Region Light Chain {J2, Chimeric Antibody} [Mice, Hybridoma Cells, Peptide Partial, 127 aa]," (1993) [online], [retrieved on 4/10/00]. Retrieved from www.ncbi.nlm.nih.gov:80.
AV8	Genbank Accession No. X65095, "M. musculus mRNA for IG Light Chain VJ Region (M-T151)," (1997) [online], [retrieved on 4/10/2000]. Retrieved from www.ncbi.nlm.nih.gov:80.
AW8	Genbank Accession No. X65087, "M. musculus mRNA for IG Heavy Chain VDJ Region (M-T151)," (1997) [online], [retrieved on 4/10/00]. Retrieved from www.ncbi.nlm.nih.gov:80.
AX8	Genbank Accession No. S50263, "Ig VH=anti-CD4 mAb M-T151 Variable Region Heavy Chain {J4, Chimeric Antibody} [Mice, Hybridoma Cells, mRNA Partial, 417 nt]," (1993) [online], [retrieved on 4/10/00]. Retrieved from www.ncbi.nlm.nih.gov:80.
AY8	Genbank Accession No. S50261, "Ig VL=anti-CD4 mAb M-T151 Variable Region Light Chain {J2, Chimeric Antibody} [Mice, Hybridoma Cells, mRNA Partial, 381 nt]," (1993) [online], [retrieved on 4/10/00]. Retrieved from www.ncbi.nlm.nih.gov:80.
AZ8	Declaration of Dr. Christian Reiter executed on November 2, 1994, filed in opposition proceeding in EP 0 511 308 (Reference A13).

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	APPLICANT John Ghrayeb <i>et al.</i>		
	FILING DATE June 29, 2001	CONFIRMATION NO. 1490	GROUP 1644

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)	
	AR9 Declaration of Dr. Margaret R. Dalesandro executed on July 1, 1998, filed in opposition proceeding in EP 0 511 308 (Reference AL3).

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